REMARKS

Claims 33-51 are pending in the application. Claims 17-32 were withdrawn in a previous amendment in response to a restriction requirement. Claim 33 was amended to address an antecedent basis issue and a grammatical error. Claim 41 was amended to address an informality. Support for the amendment to claim 41 can be found in at least Figures 2 and 3 and page 26, lines 8-15 of the original specification. Claim 45 was amended to address an informality. Support for the amendment to claim 45 can be found throughout the specification and particularly in Figure 4 and page 27, lines 1-23 of the original specification. Therefore, no new matter has been added.

Withdraw of all currently applied rejections is respectfully requested for at least the reasons set forth below.

Claim Objections

The office action has objected to claim 41 due to an informality. As stated above, claim 41 has been amended to address the informality. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the objection to claim 41.

The office action has objected to claim 47 due to an informality. Based on the comments made by the Examiner in the objection, Applicants believe that the Examiner was in fact referring to claim 45. As stated above, claim 45 has been amended to address the informality. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the objection to claim 45.

Claim Rejections under 35 U.S.C. §102

The office action has rejected claims 33-35 and 37 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Number 5,494,639 (Grzegorzewski). In particular, the office action suggests that Grzegorzewski teaches a signal driver that ***applies a signal to a transducer*** to analyze blood passing over the transducer. With all due respect to the

contentions in the office action, applicants respectfully disagree because Grzegorzewski does not teach applying a signal to the transducer.

Conventional blood analyzers measure blood coagulation in response to bulk stimulants. These conventional blood analyzers cannot differentiate between the differing mechanical properties of blood clotting without great complexity.

The novel embodiments contemplate a blood analyzer that measures certain characteristics like coagulation properties of a blood sample, and also differentiates the mechanical properties of blood clots. One way the claimed embodiment measures such various properties is by ***applying a signal to a transducer*** over which the blood flows. For example, acoustic wave signals may be applied to the blood sample and impart forces on the blood sample to provide insight into the blood's mechanical characteristics, like structural relaxation.

Grzegorzewski does not teach applying such a signal to the transducer. The office action suggests that Grzegorzewski's element 51 discloses a signal driver in communication with the transducer for applying a signal to the transducer and varying it. However, Grzegorzewski's element 51 does ***not*** apply a signal to the transducer. Instead, Grzegorzewski's element 51 is an oscillator circuit. This oscillator circuit merely receives a frequency input from a piezoelectric element 8. The piezoelectric element 8 is excited by a test fluid in a measuring chamber 7. A microprocessor 52 then measures the oscillation frequency of the oscillator 51 as the oscillator 51 is excited by the piezoelectric element 8.

However, contrary to the contention in the office action, the oscillator 51 does not apply a signal to the piezoelectric element 8. Instead, the frequency signal generated by the test fluid that interacts with the piezoelectric element 8 simply excites the oscillator circuit 51 so that the microprocessor 52 can interpret the measured frequency. Therefore, Grzegorzewski does not disclose or suggest a signal driver that applies a signal to the transducer element. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 33-35 and 37 under 35 U.S.C. §102(b) over Grzegorzewski.

The office action has suggested that the U.S. Patent Application Publication Number 2004/0072357 (Stiene) similarly teaches applying a signal to a transducer to analyze blood passing over the transducer.

Just as in Grzegorzewski, Stiene does not disclose or suggest a signal driver that applies a signal to a transducer. The office action suggests that Stiene's paragraphs [0102], [0111] and [0114] discloses a signal driver in communication with the transducer for applying a signal to the transducer. With all due respect to the contentions in the office action, nothing in the cited paragraphs discloses or suggests that any element in Stiene is a signal driver that applies a signal to a transducer.

The office action specifically suggests that the Stiene's RC oscillator is a signal driver that applies a signal to a transducer. Applicants respectfully disagree. Stiene is directed to measuring impedance or capacitance of blood that flows between electrodes 104. As the blood flows between the electrodes, contact with a clotting agent causes the blood to clot and alters the blood's impedance and capacitance. The electrodes are connected to an RC oscillator that measures a frequency that is proportional to the blood's capacitance (*Stiene* - paragraph [0114]).

This conventional frequency measurement does not involve applying a signal to the transducer. Instead, the electrodes 104 transmit a measurement signal to the RC oscillator that generates a frequency proportional to the capacitance of the measured blood sample. Therefore, Stiene does not disclose or suggest a signal is applied to a transducer by any signal driver. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 33, 48 and 51 under 35 U.S.C. §102(e) over Stiene.

The office action has rejected claims 33, 35 and 47-50 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Number 6,673,622 (Jina). In particular, the office action suggests that Jina discloses applying a ***variable signal*** to a transducer. With all due respect to the contentions in the office action, Jina does not disclose applying a variable signal to a transducer.

In some embodiments, the signals that are applied to the transducer are acoustic waves that penetrate the blood sample over a controlled penetration depth. The wave penetration depth depends on the frequency of the applied acoustic wave signal. Because multiple penetration depths are required for comprehensive measurement and analysis, ***the signal driver will vary the value of the applied*** frequency ***signal*** to the transducer. In this way, the measurement of coagulation properties can be made over a range of frequencies and thus over a range of depths. For example, the sensor may be excited over a broad range of

frequencies from1 kilohertz (kHz) to several gigahertz (gHz) so that multiple measurements can be made for a single blood sample.

The office action states that Jina's column 6, lines 30-67 discloses a signal driver for applying a variable signal to the transducer. With all due respect to the contentions in the office action, nothing in the section cited by the Examiner discloses or suggests that any element in Jina, including processor 32, varies a value of the signal to the electrodes 22.

The electrodes 22 in Jina merely measure the change in the electrical current of the total solution which varies as a function of the clotting characteristics of the blood sample. (*Jina* column 9, lines 28-33). As the cited section of Jina indicates, the processor 32 only reads the current measurement supplied by the electrodes 22. Thus, Jina does not disclose a signal driver that varies a value of the signal to the transducer. Accordingly, Applicants respectfully request withdrawal of the rejection of claims 33, 35 and 47-50 under 35 U.S.C. §102(b) over Jina.

The office action has suggested that the following references similarly teach applying a variable signal to a transducer: U.S. Patent Number 5,728,583 (Kawakami); U.S. Patent Number 5,174,291 (Schoonen) and U.S. Patent Publication Number 2003/0212347 (Sohrab).

Just as in Jina, Kawakami does not disclose or suggest applying a variable signal to a transducer. The office action states that Kawakami's column 3, lines 22-25 and column 4, lines 39-43 discloses a signal driver for driving and varying a transducer [signal] value. With all due respect to the contentions in the office action, nothing in the section cited by the Examiner discloses or suggests that an element in Kawakami, including oscillators 50a-50c, is a signal driver that varies a value of the signal to a transducer.

In general, Kawakami discloses a method and an apparatus that measures the effects of anticoagulant agents under flow conditions close to those in the body. Specifically, a method is disclosed to measure the amount or rate of adhesion of blood components on a protein layer based on the change in the basic resonance frequency of the measuring element and comparing the change value with known standards. The quartz oscillators 50a-50c are oscillated at a basic resonance frequency. Changes to that basic resonance frequency as a result of blood flow with a specific anticoagulant composition are measured by conventional means. (*Kawakami* - column 1, lines 64-67 and column 2, lines 1-3 and lines 58-63).

The changes to the basic resonance frequency created by the varying anticoagulant containing blood flow and the conventional means for measuring the resonance frequency does not apply a variable signal to the transducer. The oscillators 50a-50C in Kawakami are merely oscillated at a basic resonance frequency. As Kawakami indicates, the conventional measurement means measures the resonance frequency of the oscillators 50a-50C. Kawakami does not disclose or suggest that the basic resonance frequency of the crystal oscillators 50a-50c is varied and thus, Kawakami does not disclose a signal driver that varies a value of the signal to the transducer. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the §102(b) rejection of claims 33 and 37-40 over Kawakami.

Just as in Kawakami, Schoonen does not disclose or suggest applying a variable signal to a transducer. The office action states that Schoonen's element 12 in column 10, lines 53-60 discloses a signal driver in communication with the transducer for applying a signal to the transducer and varying it. With all due respect to the contentions in the office action, nothing in the section cited by the Examiner discloses or suggests that any element in Schoonen, including potentiostat 12, is a signal driver that varies a value of the signal to a transducer.

In Schoonen, an electrode is connected via a jacketed 2-core cable to a potentiostat 12 which maintains a fixed voltage (-0.6 V) on the electrode 13 and measures the current strength caused by the oxygen. The measuring cell specificity to oxygen is obtained by applying a negative voltage of 0.6 V to the operating electrode 13 with respect to the reference electrode 15. Electrons of the operating electrode 13 will then reduce the oxygen passing through the membrane. The current strength measured with the potentiostat 12 is proportional to the oxygen concentration and measured with the ammeter. (*Schoonen* - column 10, lines 30-34 and lines 50-57).

The applied voltage on the electrode 13 is not a variable signal to the electrode 13. Instead, the fixed voltage of -0.6V is applied to the electrode 13 by the potentiostat 12 and the potentiostat 12 merely measures the current strength of the sample passing through the membrane. Thus, Schoonen does not disclose a signal driver that varies a value of the signal to the transducer. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the §102(b) rejection s of claim 33 and 43 over Schoonen.

Just as in Schoonen, Sohrab does not disclose or suggest applying a variable signal to a transducer. The office action states that Sohrab's paragraph [0049] discloses a signal driver in communication with the transducer that applies a signal to the transducer and can vary the value of that signal. With all due respect to the contentions in the office action, nothing in the paragraph cited by the Examiner discloses or suggests that any element in Sohrab is a signal driver that varies a value of a signal to a transducer.

In paragraph [0049], Sohrab discloses that the electrodes will measure a varying current that is proportional to the amount of analyte in the chamber, wherein the reagents added to the chamber will alter the current conducting characteristics of the chamber contents in proportion to the amount of analyte present. There is no disclosure or suggestion in paragraph [0049] that any signal is varied to the electrodes. Such a signal variation is not suggested since it is the change in analyte composition in the sample that causes the change in the measurement that the electrodes make. Thus, Sohrab does not disclose or suggest a signal driver that varies a value of the signal to the transducer. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the §102(e) rejections of claim 33 and 36 based on Sohrab.

The office action has rejected claims 33 and 42 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Number 7,223,365 (Freiherr Von Der Goltz, hereinafter "Freiherr"). In particular, the office action states that Freiherr teaches **a *signal processor in communication with a transducer element that determines a characteristic of the blood as a function of the blood's response to a signal***. With all due respect to the contentions in the office action, applicants respectfully disagree because none of the cited elements of Freiherr, including elements 9 and 18, teach a signal processor that determines a characteristic of the blood as a function of the blood's response to a signal.

In order to determine blood characteristics like coagulation properties, an embodiment contemplates an electronic section or a signal processing section of the sensor that excites the transducer over a frequency range of a single KHz to several GHz and detects changes in the operational parameters of the transducer. These changes reflect the response of the blood sample to the introduced acoustic waves. The detected changes include variations in the transfer function, the resonant frequency, the resonant amplitude, the phase and the quality factor. These measured changes in the operational parameters are processed, related to the

targeted blood property (the characteristic coagulation factors for instance), and displayed. Thus, the signal processing section is capable of performing the necessary analysis required to calculate the coagulation factors, which are determined as a function of the measured response of the blood sample to the signal. Accordingly, the signal processor comprises a system of accompanying electrical oscillatory circuits in which resonant transducer structures control their frequency, phase and the amplitude. See page 23, line 28 to page 24, line 10 of page 24 of the original specification.

Generally, Freiherr discloses a method and a device for determining the hemostasis functions of whole blood or plasma. (*Freiherr* - Abstract). Examples of the hemostatic functions of the blood or plasma sample that are determined as a result of measurements taken are shown in Figures 25-29 of Freiherr. In operation, Freiherr discloses that the controller 18 controls the drive of motor 17, which in turn controls the motion of piston 4. The manipulation of piston 4 affects the pressure of the sample in the pressure gauge chamber 3. The pressure gauge 9 is connected to the pressure gauge chamber 3 to measure the pressure of chamber 3. The pressure gauge 9 is also connected to the controller 18 so that the controller 18 can control the movement of piston 4 (through motor 17) as a function of the pressure measured by pressure gauge 9. (*Freiherr* - column 10, lines 11-46).

Although the controller 18 measures the response (the pressure in pressure gauge chamber 3) via the pressure gauge 9 to the signal that modulates the position of the piston 4, the controller 18 does *not* determine a characteristic (hemostasis function) of the blood or plasma sample as a function of that pressure measurement. Freiherr does *not* disclose or suggest that the controller 18 is capable of the analysis required to be made with the measurements taken to determine the hemostasis functions of the blood or plasma as those functions are disclosed in Figures 25-29 of Freiherr. Further, Freiherr does not disclose or suggest that the controller 18 has the capability to measure the other variables required to determine the hemostasis functions such as the volume in the cylinder 25 or the volumetric flow through the reaction device 39 after a certain predetermined time has elapsed. (*Freiherr* - column 6, lines 57-60). Therefore, Freiherr does not disclose or suggest a signal processor that determines a characteristic of the blood as a function of a response of the blood to a signal. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the §102(e) rejections of claim 33 and 42 over Freiherr.

Claims 34-40 and 42-51 are considered to be patentable over the cited references for at least the reason that claims 34-40 and 42-51 depend from a patentable base claim and recite further patentable elements. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the §102(b) and §102(e) rejections of claims 34-40 and 42-51.

Claim Rejections under 35 U.S.C. §103

The Examiner has rejected claim 41 under 35 U.S.C. §103(a) as being unpatentable over Jina. Applicants respectfully traverse this rejection.

Claim 41 is believed to be patentable over Jina for at least the reason that claim 41 depends from a patentable base claim and recites further patentable elements. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the §103(a) rejection of claim 41.

As a concluding matter regarding the prior art rejections, Applicants direct to the Examiner's attention M.P.E.P. § 904.03, which states in part:

The examiner is not called upon to cite all references that may be available, but only the "best." (37 CFR 1.104(c).)

Applicants believe that this directive is generally supportive of an efficient prosecution process.

Applicants note that while rejecting all but one dependent claim under §102, the office action has rejected the independent claim 33 with seven different references. This examination strategy has required Applicants to address each of the seven references in order to traverse the rejection of claim 33 alone. As a result, the Examiner must now address multiple rebuttal arguments for the rejection of claim 33 made over these seven different references.

Applicants respectfully point out that the Examiner's initial rejection strategy has led to an inefficient prosecution process, wherein Applicants and the Examiner must continue

to address arguments across each and every one of these seven references until all outstanding issues are addressed for claim 33.

Claim Rejections under §112

The office action has rejected claims 33-51 under 35 U.S.C. §112, second paragraph, for being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner states that the phrase "biological sensing media" is not supported by the original specification. Applicants respectfully traverse these rejections.

In addition to the reference to "bio-sensing element" in Figure 2, on page 25, lines 24-33 of the original specification, it is stated:

> Thereafter, the blood sample is exposed to a sensing element, preferably a biologically active substance such as collagen or thromboplastin, which is selectively responsive to a measurand of interest such as platelets, blood cells, or a selected protein. When the biomeasurand interacts with the sensing element, microscopic physical, chemical, and/or biochemical changes are produced. These microscopic changes cause the macroscopic physical changes in the biosensing element, which are converted by the acousto-mechanical transducer into a measurable electric signal output.

Support for the phrase "biological sensing media" in claim 33 can be drawn from the referenced "bio-sensing element" in Figure 2, from the referenced biologically active substance, sensing element and biosensing element in the above cited. Therefore, there is adequate support in the original specification for the phrase "biological sensing media."

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the §112 rejection of claims 33-51.

Conclusion

Insofar as the Examiner's objections and rejections having been adequately addressed, Applicants believe that the current application, including claims 33-51, is in condition for allowance and such action is respectfully requested.

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